Recording that elusive rhythm

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Technology: Implantable loop recorder

Use: The implantable loop recorder is a cardiac monitor that is implanted in patients with recurrent unexplained syncope to provide up to 14 months of cardiac monitoring. This allows the clinician to obtain a symptom–rhythm correlation during infrequent spontaneous symptoms such as syncope or presyncope.

History: Conventional monitoring techniques in patients with syncope include inpatient telemetry and Holter monitoring. These techniques are limited by relatively brief monitoring periods, however, and it is unlikely that the rhythm profiles will provide sufficient diagnostic information for patients with infrequent symptoms. Advances in pacemaker technology in the mid-1980s that enabled us to record the rate of the detected rhythm eventually led to the innovative concept that some patients might benefit from prolonged cardiac rhythm monitoring. George Klein pioneered the use of the implanted syncope monitor in patients in which an arrhythmia was suspected but could not be documented because episodes were too infrequent. After promising results were obtained in 16 such patients² engineers from Medtronic (Mississauga, Ont.) worked with Klein to develop a prototype device. A pilot study was undertaken involving 24 patients with unexplained syncope, and a diagnosis was obtained in 21 (88%) of those patients within 2 years of the implantation of the recorder;³ these successful results led to the development of a commercially available recorder. The Health Protection Branch of Health Canada and the Food and Drug Administration in the United States approved the clinical use of the device in 1998 after a multicentre clinical trial involving 84 patients in Canada and Europe with unexplained syncope⁴ demonstrated the safety and efficacy of the device.

Promise: The implantable loop recorder is emerging as an ideal tool for patients who require long-term monitoring for unexplained syncope. In those who have been diagnosed with the aid of the implanted loop recorder, the appropriate treatment has led to the elimination of syncope and has allowed patients to return to work and to drive again. This has also prevented further low-yield investigation of patients with conventional diagnostic techniques.

Problems: The major limitations to the implantable loop recorder are its requirement for subcutaneous insertion and the cost. The use of this biomedical device requires familiarity with implantation techniques and programming, and the cost is considerably higher than that of other monitoring techniques, such as Holter monitoring and the conventional wearable loop recorder. Nonetheless, economic analyses suggest that although the procedure compares favourably with other invasive tests used in cardiology, it should be reserved for patients in whom less expensive tests have failed to provide a diagnosis.

Prospects: This new technology is at a growth phase in terms of





The implantable loop recorder, middle, which continuously records a single-lead ECG. Up to 40 minutes of preceding signal can be stored after an episode of spontaneous syncope by holding the activator, left, over the recorder and pressing the activation button. The device measures $61 \times 19 \times 8$ mm, with 2 sensing electrodes 37 mm apart within its shell. The recorder weighs 17 g and has a volume of 8 mL, slightly smaller than a standard VVI pacemaker.

its implementation in clinical practice. As specialists become more familiar with its use and indications, it is likely that the implantable loop recorder will be used more often in everyday practice. Studies currently under way at the University of Western Ontario (London, Ont.) to compare the results from an implanted loop recorder with those of conventional diagnostic tests may suggest utilizing the implantable loop recorder at an earlier stage in the diagnostic cascade. Ongoing development of the device is focusing on smaller size, larger memory capacity and the ability to automatically detect high and low heart rates without patient activation.

Vignette: A 74-year-old man presented to the Emergency

Department after experiencing his third episode of syncope in a 2-year period. On this occasion he had been out in his garden when he suddenly lost consciousness, fell and sustained a soft-tissue injury to his face. Upon arrival to the hospital, his vital signs were stable and physical examination normal. Results of preliminary tests, including an electrocardiogram, were normal. The patient's primary care physician had previously obtained a 48-hour Holter monitor, an echocardiogram, an exercise test and a neurology referral accompanied by an EEG, carotid Doppler and CT scan of the brain; the test results were all negative. After the third episode of syncope the patient was referred to a cardiologist for further tests. A loop recorder was implanted after an electrophysiology study was inconclusive. Four months later the patient experienced recurrent syncope with minimal warning, and the implanted device documented a period of asystole lasting 8 seconds. The device was promptly removed, and a pacemaker was implanted. The patient has since been free of syncope.

Competing interests: Drs. Krahn, Klein, Yee and Skanes have conducted research to evaluate Medtronic products and have received speaker fees and travel assistance to attend meetings from Medtronic. Dr. Klein is a consultant to Medtronic and participated in the development of implantable loop recorder technology.

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